

REMARKS

Claims 1-3, 5-8, 16-18, 21-23 were pending for purposes of the instant Office Action.

Claims 4 and 15 were previously canceled. Claims 9-14 and 19-20 were previously canceled without prejudice in response to a Restriction Requirement. Claim 1 is currently amended as shown above, without prejudice. Applicants submit that no new matter has been added by virtue of this amendment.

Accordingly, claims 1-3, 5-8, 16-18 and 21 to 23 remain pending.

Enablement Rejections

Claims 1 to 3, 5 to 8, 16 to 18, and 21 to 23 were rejected under 35 U.S.C. § 112, first paragraph, allegedly for lack of enablement for a method for detecting cancer, including hepatic cancer.

As admitted in the Office Action: "A review of the specification discloses support for a method for detecting cancer by detecting soluble GPC3 in a test or clinical sample (p.1, first paragraph, p.5)." See Office Action, page 5, lines 4-5.

In light of the Examiner's comments and to expedite prosecution of this application, claim 1 has been amended without prejudice to recite in relevant part: "A diagnostic method for GPC3 protein expressing cancer, said method comprising detecting a soluble GPC3 protein level in a test sample selected from the group consisting of blood, serum and plasma, and determining whether said detected soluble GPC3 level in the test sample is greater than a control level of GPC3 in normal non-cancerous blood, serum or plasma."

Applicants respectfully direct the Examiner's attention to the definition of "diagnosis" and "diagnostic" as found in "Churchill's Medical Dictionary", a copy of the relevant portion is attached herewith as Exhibit A, which recites in relevant parts:

diagnosis: "1. A determination of the nature or identity of a disease, typically based on an analysis of signs and symptoms, the patient's medical history, and often on the results of laboratory tests."

Diagnostic: "2. Contributing to or useful in the process of reaching a diagnosis."

Applicant note that the recitation of the term “diagnosis” as found in “Churchill’s Medical Dictionary”, a copy of the relevant portion is attached herewith as Exhibit A, further states in relevant part: “The use of laboratory findings to establish a diagnosis without reference to the subject’s history or physical findings.”

Therefore the claim is enabled because a person of ordinary skill in the art would be able to measure the GPC3 in a test sample, and determine whether a test sample (blood, serum, or plasma) contains “greater levels” of GPC3 than the levels of GPC3 found in a normal control, and thereby be enabled to use said results for a diagnostic method for GPC3 protein expressing cancer. Support for the foregoing may be found in paragraph [0007] of U.S. Patent Publication No. 2006/0014223 of the present specification which recites: “The expression of GPC3 protein has also been detected in cancer cell lines other than hepatic cancer cell lines, such as lung cancer, colon cancer, mammary cancer, prostate cancer, pancreatic cancer, and lymphomas. Hence, GPC3 may possibly be applied to the diagnosis of hepatic cancer as well as many other cancers.”

Applicants respectfully submit that one of ordinary skill can determine whether a test sample (blood, serum, or plasma) contains “greater levels” of GPC3 than the levels of GPC3 found in a normal control, and thereby use the results to diagnose GPC3 protein expressing cancer, as disclosed in the subject application.

In view of the foregoing, it is respectfully submitted that the subject claims are enabling, and reconsideration and withdrawal of the rejection under 35 USC 112, first paragraph, is respectfully requested.

Rejection Under 35 U.S.C. § 112, first paragraph- Written Description

Claims 1 to 3, 5 to 8, 16 to 18 and 21 to 23 were rejected under 35 U.S.C. § 112, first paragraph. It is alleged that the specification does not contain a written description of the claimed invention of claims 1 to 3, 5 to 8, 16 to 18 and 21 to 23. See Office Action, page 4, lines 20-21.

The Office Action states that: “[t]he limitation of “a method for identifying subjects suspected of having cancer” and “a test sample obtained from a subject suspected of having

cancer”, claimed in claims 1-3, 5-8, 16-18, 21-23 has no clear support in the specification and the claims as originally filed.” See Office Action, page 5, lines 1-3.

Applicants respectfully submit that the claim language: “a method for identifying subjects suspected of having cancer” and “a test sample obtained from a subject suspected of having cancer” is inherently included in the present invention as disclosed in the original specification and does not represent new matter.

However, to expedite the prosecution of the present application, independent claim 1 has been amended without prejudice in relevant part to delete the phrases: “a method for identifying subjects suspected of having cancer” and “a test sample obtained from a subject suspected of having cancer”.

As admitted in the Office Action: “A review of the specification discloses support for a method for detecting cancer by detecting soluble GPC3 in a test or clinical sample (p.1, first paragraph, p.5).” See Office Action, page 5, lines 4-5.

Claim 1 has been amended without prejudice to recite in relevant part: “A diagnostic method for GPC3 protein expressing cancer, said method comprising detecting a soluble GPC3 protein level in a test sample selected from the group consisting of blood, serum and plasma, and determining whether said detected soluble GPC3 level in the test sample is greater than a control level of GPC3 in normal non-cancerous blood, serum or plasma.”

Claims 2 to 3, 5 to 8, 16 to 18 and 21 to 23 depend either directly or indirectly from claim 1.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection to independent claim 1 and dependent claims 2- to 3, 5 to 8, 16 to 18 and 21 to 23 under 35 U.S.C. § 112, first paragraph.

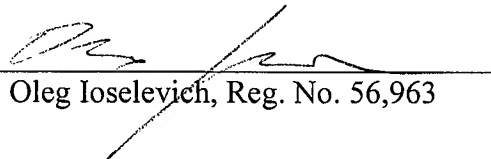
Appl. No. 10/526,508
Amdt. dated February 25, 2010
Reply to Office Action of October 26, 2009

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CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

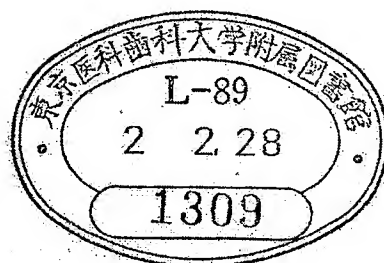
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APPENDIX A

CHURCHILL'S
Illustrated MEDICAL
DICTIONARY



CHURCHILL LIVINGSTONE
New York, Edinburgh, London, Melbourne

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Churchill's illustrated medical dictionary.

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sive doses of adrenal corticosteroids or in association with endogenous hypercortisolism (Cushing syndrome). It is characterized by a moderate requirement for insulin, resistance to ketoacidosis, and a relatively low rate of microvascular and macrovascular complication. **subclinical d.** LATENT DIABETES. **thiazide d.** Glucose intolerance produced by the administration of derivatives of benzene disulfonamide, such as hydrochlorothiazide. The mechanism is not established but may be related to diuretic-induced hypokalemia. **type-1 d.** INSULIN-DEPENDENT DIABETES MELLITUS. **vasopressin-resistant d.** insipidus NEPHROGENIC DIABETES INSIPIDUS. **Young's d.** Glucose intolerance induced experimentally in animals by protracted administration of pituitary extract specifically growth hormone. Also *metahypophyseal diabetes*.

diabetic \di'əbet/ik\ [*diabet(es)* + -IC] 1 Of, relating to, or affected by diabetes, especially diabetes mellitus. 2 One affected by diabetes, especially diabetes mellitus.

diabetogenic \di'əbē'tojen/ik\ [*diabet(es)* + *o* + -GENIC] Causing diabetes. Also *diabetogenetic*.

diacetyl-N-allylnormorphine DIACETYNALORPHINE.

diacetyldapsone ACEDAPSONE.

diacetylmorphine HEROIN.

diacetyltannic acid ACETANNIN.

diacetylnalorphine A structural and functional analogue of nalorphine, with greater potency. It is used primarily in the treatment of morphine poisoning and addiction. Also *diacetyl-N-allylnormorphine*.

diachoresis \di'əkōrē'sis\ DEFECACTION.

diacnosis \di'əklō'sis\ OSTEOCLASIS.

diaclast \di'əkləst\ [DIA- + -CLAST] An instrument used to perforate the fetal skull for a craniectomy.

diacrinous \di'əkrī'nəs\ [DIA- + Gk *krin(ein)* to separate + -OUS] Of or relating to secretion of a glandular product as a homogeneous fluid rather than in the form of globules or granules. Compare PTYOCRINOUS.

diacrisis \di'əkrī'sis\ [Gk *diakrisis* (from *diakrinein* to distinguish, discriminate, from DIA- + *krinein* to separate, choose) determination, decision] DIAGNOSIS.

diacritic \di'əkrīt/ik\ DIAGNOSTIC.

diacylglycerol Glycerol acylated on two of its hydroxyl groups, usually 1,2. Diacylglycerols are intermediates in the biosynthesis of fats (triacylglycerols) and of phospholipids. Also *diglyceride*.

diadermic \di'ədər/mik\ PERCUTANEOUS.

diadochocinesia \di'əd'əkōsīnē'zhə \ DIADOCHOKINESIA.

diadochokinesia \di'əd'əkōkīnē'zhə \ [Gk *diadoch(e)* succession, relay, taking turns + *kinēs(is)* movement + -IA] The ability to perform rapid, repetitive, coordinated movements such as repeated supination and pronation of a hand and forearm; the rapid performance of opposite motor behaviors. Also *diadochocinesia*, *diadochokinesis*. Adj. *diadochokinetic*, *diadochocinetic*.

diagnose \di'əgnōs\ [back-formation from DIAGNOSIS] To determine the nature or identity of (a disease), as by an analysis of signs and symptoms.

diagnosis \di'əgnō'sis\ [Gk *diagnōsis* (from *diagnōskein* to distinguish, discriminate, diagnose, from *dia-* apart, between + root of *gnōsis* knowledge, recognition) discernment, means of distinguishing or resolving, diagnosis] (*pl.* diagnoses) 1 A determination of the nature or identity of a disease, typically based on an analysis of signs and symptoms, the patient's medical history, and often on the results of laboratory tests. Also *diacrisis*. 2 The art or process of making such a determination. **d. by exclusion** Identification of a patient's disease by eliminating all other

known possibilities. Also *exognosis*.

clinical d. The use of a subject's history, a physical examination, and laboratory findings to establish a diagnosis. **cytologic d.** Diagnosis arrived at by the microscopic study of exfoliated cells.

differential d. 1 The process of making a diagnosis by comparing and analyzing the similarities and differences between the signs, symptoms, and other findings associated particularly with two or more diseases sharing certain characteristics. By this means, similar conditions are systematically eliminated from consideration. 2 A diagnosis made on this basis. Also *differentiation*.

direct d. Rapid diagnosis made possible by the demonstration of characteristic morphologic lesions. **d. ex juvantibus** The identification of disease made on the basis of the patient's response to treatment.

laboratory d. The use of laboratory findings to establish a diagnosis without reference to the subject's history or physical findings.

pathologic d. Diagnosis arrived at by the observation of gross and microscopic findings affecting an organ or tissue.

physical d. Diagnosis made on the basis of information gained by physical examination of the patient.

quick-section d. A diagnosis that is derived from the examination of a frozen or cryostat section of diseased tissue. This method is used particularly during the course of a surgical operation when the surgeon requires guidance before proceeding further.

diagnostic \di'əgnās'tik\ [Gk *diagnōstikos* able to distinguish, pertaining to diagnosis] 1 Of, for, or relating to diagnosis. 2 Contributing to or useful in the process of reaching a diagnosis. For defs. 1 and 2 also *diacritic*.

diagnostician \di'əgnāstīsh'ən\ 1 A practitioner considered with respect to the ability to make accurate diagnoses, as a *good diagnostician*. 2 An expert or specialist in diagnosis.

diagnostics \di'əgnās'tiks\ The medical science concerned with diagnosis.

diagram \di'əgram\ A plan or outline that graphically represents the structure of an object or illustrates relationships.

Berkow d. A diagram of the body surface that uses the Berkow scale for estimating the extent of a burn. It is used to calculate the size of a burn as a percentage of total body surface.

burn d. Any of several diagrams of the body surface, dividing it into percentages used to calculate the size of a burn in terms of percentage of total body surface.

vector d. A diagram, based on the scalar electrocardiogram, demonstrating the magnitude, sense, and direction of the electromotor forces of the heart throughout a cardiac cycle.

diagrammatic \di'əgrəmat'ik\ Based on or consisting of a diagram.

diagraph \di'əgraf\ [DIA- + -GRAPH] An instrument used to record the outline of one or more parts of the body.

diakinesis \di'əkinē'sis\ [DIA- + KINESIS] The last phase of prophase I of meiosis, in which chromosome contraction reaches its maximum and the tetrad form can be observed. Chromosomes show two types of coiling, referred to as major and minor coils. During diakinesis the nucleolus disappears and the nuclear envelope is disrupted.

Diakiogiannis [*Diakiogiannis*, Greek physician, flourished 20th century] See under SIGN.

dial / astigmatic d. A pattern of evenly spaced radial lines used to detect the presence of an astigmatic refractive error by the difference of blackness seen in the meridian of astigmatic error.

dialysance \di'al/īzəns\ [*dialysis* + -ANCE] The rate of removal of a substance per unit of difference in the concentrations of the substance in blood and in the bath fluid of the artificial kidney.

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